

In re: Odidi et al.
Serial No. 09/845,497
Docket No. 9577-25

- 8 -

Remarks/Arguments

Claims 1, 6-9, 11, 15-17 and 21-34 remain in this application. Applicant acknowledges the allowance of claims 31 and 32.

Claim Rejections- 35 U.S.C. §103(a)

Claims 17, 21, 23, 30 and 33 are continued to be rejected under 35 U.S.C. §103(a) as being unpatentable over Japanese Patent No. 03197421 to Hirashima. The Examiner asserts that the Applicant does not provide a showing that the difference in the amounts of PEG and ethylcellulose in Hirashima and the instant invention would materially impact the invention. Further the Examiner asserts that the Applicant does not provide data showing that the 10% difference in the ethylcellulose and the PEG would make the coat permeable and insoluble at any pH.

The Applicant respectfully disagrees with the Examiner. As the Examiner is aware, the reference must be considered as a whole and must suggest the desirability and thus the obviousness of making the claimed combination. Hindsight cannot be used. There also must be a reasonable expectation of success for the obviousness determination. Furthermore, the prior art reference must suggest all of the claim limitations. The initial burden is on the Examiner to provide the suggestion of desirability of doing what the claims recite.

Hirashima discloses a coated tablet of ascorbic acid (vitamin C) for a release profile of up to about 12 hours. The coating provided by Hirashima is solely for the release of ascorbic acid. In contrast, with respect to Independent Claims 17, 23 and 33, these claims are directed to an extended release pharmaceutical active formulation comprising an encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 to less than 50% by weight of polymer. The pharmaceutical may be a variety of actives as is recited for example in claim 34 and these actives are very different with different properties to the ascorbic acid of Hirashima. Thus the present claims provide for a pharmaceutical active with an encasement coating that addresses the extended release of the variety of pharmaceutical actives. The encasement coating presently recited in the claims is different to that of Hirashima and Hirashima does not at all disclose or suggest the claimed recited components of the coating. As is stated in the description at page 3, the present encasement coating is not permeable.

In re: Odidi et al.
Serial No. 09/845,497
Docket No. 9577-25

- 9 -

The coating of Hirashima may comprise ethyl cellulose but the amount does not fall within the range of about 5 to less than 50% by weight of polymer in the coat. 12 g of ethyl cellulose and 8 g of polyethylene glycol corresponds to 60% ethyl cellulose and 40% polyethylene glycol, respectively. The percentage of ethyl cellulose, 60%, is a percentage that clearly does not fall within the claimed ranges. Again, it is submitted that it would not be obvious to one of skill in the art to conclude that the coat of Hirashima would be non-permeable and soluble in a pH of above about 5.0. As the Examiner may be aware, the amounts and combinations of the amounts of polymers provides various properties to the final coating. That is why many coatings in the art may share certain common elements such as PEG, however, it is the novel relative amounts and combinations of such together with the active, that provide novel and unique properties beneficial to the release of the desired active.

To reiterate, to establish *prima facie* obviousness of a rejected claim, the applied art of record must teach or suggest each and every feature of a rejected claim and the motivation to provide such. See M.P.E.P. §2143.03. Hirashima does not teach or suggest these properties of the coat or the specific percentage(s) and thus the coating of Hirashima would have different properties (ie. be permeable) as is evident in that ascorbic acid is being released for only up to about 12 hours. The polyethylene glycol of the coat of Hirashima would dissolve in solution producing porous channels in the coat, while maintaining its' integrity even after the active had leached out. The coat of Hirashima would not be soluble at any pH. In contrast, the coat of the claimed invention is non-permeable and soluble in a pH of above about 5.0 as is clearly taught in the description.

In addition, with respect to Claims 17 and 23, Hirashima does not teach or suggest the inclusion of about 0.5%-30% by weight polyethylene glycol or 0.5%-30% by weight plasticizer comprising polyethylene glycol, respectively, in the coat. The polyethylene glycol of Hirashima is outside the ranges of the components of the claimed invention.

For these reasons, it is respectfully submitted that independent Claims 17, 23 and 33 are patentable over Hirashima and consequently, Claims 21 and 30, which are dependent, or ultimately dependent, from Claim 17, are also patentable over Hirashima.

Claim Rejections- 35 U.S.C. §112, first paragraph

Claims 1, 6-9, 11, 15, 16, 22, 24-29 and 34 are rejected under 35 USC 112, first paragraph. The Examiner asserts that the specification provides support for the

In re: Odidi et al.
Serial No. 09/845,497
Docket No. 9577-25

- 10 -

encasement of the entire formulation. Solely to further the prosecution of the application claim 1 has been so amended thus obviating this rejection.

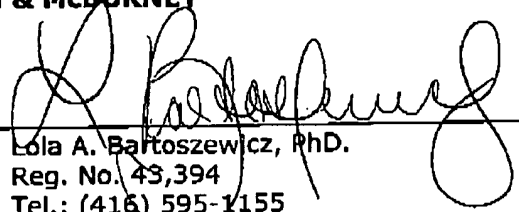
Conclusion

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of all of the pending claims 1, 6-9, 11, 15-17, 21-34, and the prompt issuance of a Notice of Allowability are respectfully solicited.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Sim & McBurney's Account No. **192253**, referencing docket number 9577-25 LAB.

Respectfully submitted,
SIM & MCBURNEY

By


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